

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|                                   |   |                     |
|-----------------------------------|---|---------------------|
| In re continuation-in-part patent | ) | Before the Examiner |
| application of:                   | ) |                     |
|                                   | ) |                     |
| Arnold Neracher                   | ) | Art Unit 3762       |
|                                   | ) |                     |
| Serial No.                        | ) |                     |
|                                   | ) |                     |
| Filed October 12, 2001            | ) |                     |
|                                   | ) |                     |
| HYPODERMIC INJECTION DEVICE       | ) | October 12, 2001    |

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

Prior to computing the filing fees, please cancel claims 1-67, without prejudice  
and insert in lieu thereof new claims 68-111 as follows:

68. A propulsion system suitable for a single-use or a multi-use injection device, said  
propulsion system comprising a container and a primary source of potential energy for  
propelling a fluid to be injected with sufficient pressure through an orifice to create a jet

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enabling subcutaneous or intracutaneous delivery of the fluid, the primary source of potential energy principally in the form of a compressible substance under pressure within the container, whereby said potential energy is substantially compression energy of said compressible substance, wherein said substance is a liquid, solid, or other non-gaseous substance as defined at ambient temperature and pressure.

69. Propulsion system according to claim 68, wherein the compressible substance has a volumetric compressibility ( $dV/V$ ) at said pressure within the container greater than 1.2 times the volumetric compressibility of water.

70. Propulsion system according to claim 68, further comprising a secondary potential energy source adapted to propel the fluid to be injected at a pressure lower the pressure generated by the primary source of potential energy.

71. Propulsion system according to claim 70, wherein the secondary potential energy source is a gas, as defined at ambient pressure and temperature, under pressure within the container in a container portion separate from a container portion housing the primary compressible substance, or dissolved in or mixed with the primary compressible substance.

72. Propulsion system according to claim 70, wherein the secondary potential energy source is an elastic member such as a spring, or opposed magnets, compressed in the container.

73. Propulsion system according to claim 68, wherein the compressible substance is a visco-elastic liquid, an elastic solid, or soft matter.

74. Propulsion system according to claim 73, wherein the compressible substance belongs to the family of polysiloxanes.

75. Propulsion system according to claim 74, wherein the solid is vulcanised silicon rubber.

76. Propulsion system according to claim 68, wherein the pressure of the compressible substance in the container prior to use exceeds 200 bars.

77. Propulsion system according to claim 68, wherein the compressible substance is put under pressure in the container by reducing the volume thereof after being filled with said compressible substance.

78. Propulsion system according to claim 77, wherein the volume of compressible substance is reduced by a permanent deformation of a wall of the container.

79. Propulsion system according to claim 77 wherein the volume of compressible substance is reduced by a pressure generating mechanism (125) of the device displacing a piston (112).

80. Propulsion system according to claim 68, further comprising a movable or breakable separating or pressure transmitting member enclosing the compressible substance in the container, the separating or pressure transmitting member being adapted to be released or broken to enable the compressible substance to transmit pressure to said fluid to be injected.

81. Propulsion system according to claim 80, wherein said separating or pressure transmitting member is in the form of a piston maintained in position prior to use by retaining means.

82. Propulsion system according to claim 81, wherein the retaining means comprise a rod (17, 17', 17'', 17''', 17''') retaining the piston (5, 5', 5'') prior to use, in a position where the compressible substance 7 is compressed.

83. Propulsion system according to claim 68, wherein the propulsion system forms a unit in which the compressible substance is under pressure, the unit being assemblable to an ampoule or capsule containing the fluid to be injected.

84. Propulsion system according to claim 80, wherein the piston (5'', 5''') is mounted substantially floatably in the container.

85. Propulsion system according to claim 80, wherein the separating or pressure transmitting member is a deformable wall (49, 49', 49", 49''').

86. Propulsion system according to claim 68, further comprising retaining means comprising a plug (40, 40', 45, 47, 47') for maintaining the pressure of the compressible substance in the container prior to use by closing an orifice or a passage (16, 44, 44', 44", 44''').

87. Propulsion system according to claim 86, wherein the plug (40, 40', 47, 47') is a mechanical plug that may be displaced to liberate said passage or orifice.

88. Propulsion system according to claim 86, wherein the plug (44) is made of a material that may be decomposed by external solicitation.

89. Propulsion system according to claim 86, wherein the plug (47') is attached to a movable wall or piston (54) arranged in a container portion (9", 9''') containing the compressible substance such that, prior to use, a small amount of the compressible substance is positioned in a rear portion (60') of the container so as to maintain the piston in a position where the plug (47') blocks the passage (44, 44''').

90. Propulsion system according to claim 89, further comprising means to open the rear portion (60') for reducing pressure in this portion and causing displacement of the piston (44) and the plug (47') towards the rear.

91. Propulsion system according to claim 90, wherein the opening means of the rear portion (60') comprise a rear plug (63) provided with a rupture zone (66).

92. Propulsion system according to claim 90, wherein the opening means of the rear portion (60') comprise a rupture zone (58) in the wall of the container.

93. Propulsion system according to claim 89, wherein the movable piston comprises one or more passages (57) interconnecting the rear portion (60') to the remainder of the container portion containing the compressible substance.

94. A propulsion system suitable for a single use injection device, said propulsion system comprising a container and a source of potential energy for propelling a fluid with sufficient pressure through an orifice to create a jet enabling subcutaneous or intracutaneous delivery of the fluid, wherein the source of potential energy comprises a first compressible substance (7, 7') at a first pressure P1 within the container and at least a second compressible substance (7'', 77) at a second pressure P2 lower than P1, whereby said potential energy is substantially compression energy of said substances, said first substance being a liquid, solid, or other non-gaseous substance as defined at ambient temperature and pressure.

95. Propulsion system according to claim 94, wherein the first compressible substance belongs to the family of polysiloxanes.

96. Propulsion system according to claim 94, wherein the first compressible substance (7) is enclosed in a first section (8a) of the container by a movable or breakable separating or pressure transmitting member adapted to be released or broken to enable the compressible substances to transmit pressure to said fluid to be injected.

97. Propulsion system according to claim 94, further comprising a movable partition (89) separating a first section (8a) of the container comprising the first compressible substance from a second section (8b) of the container comprising the second compressible substance.

98. Propulsion system according to claim 97, wherein a first section (8a) of the container comprising the first compressible substance is separated from a second section (8b) of the container comprising the second compressible substance by a reduced section passage (91) blocked by a plug portion (92) prior to use.

99. Propulsion system according to claim 94, wherein the second compressible substance is a liquid or solid substance similar to the first compressible substance.

100. Propulsion system according to claim 94, wherein the second compressible substance is a gaseous substance, as defined at ambient temperature and pressure.

101. A single-use hypodermic injection device for subcutaneous or intracutaneous administration of a fluid product to be injected, such as a medicament, a vaccine or another pharmaceutical composition, comprising a propulsion system according to claim 68, a fluid product to be injected and a nozzle portion having an orifice.

102. Device according to claim 101, wherein the pressure of the compressible substance is sufficient to produce a jet of fluid attaining supersonic speed.

103. Device according to claim 101, wherein the fluid product to be injected (2) is contained in a separate ampoule or capsule or rigid cartridge, for mounting in or to the propulsion system.

104. Device according to claim 103, wherein the ampoule, capsule or rigid cartridge includes the nozzle portion (11').

105. Device according to claim 103, wherein the ampoule comprises a flexible or deformable wall fixed to the nozzle portion to contain the fluid to be injected therein.

106. Device according to claim 103, wherein the ampoule is inserted into the container and held therein by permanently deformed portions (10') of the container.

107. Device according to claim 103, wherein the ampoule comprises a breakable partition such as a tube (76) that may be broken to actuate the device.



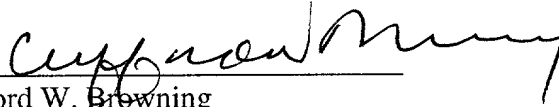
108. Device according to claim 107, wherein the tube is dimensioned to enable the creation of a shock wave resulting from the dynamic pressure of the compressible substance in the container portion containing the liquid to be injected following rupture of the tube.

109. Device according to claim 101, further comprising a skin piercing member (93).

110. Device according to claim 109, wherein the skin piercing member forms said nozzle portion (11") and defines said orifice (16").

111. Device according to claim 109, wherein wherein the skin piercing member is movable and maintained in a retracted position by elastic buffer means (96, 96'), such that a piercing tip (97) thereof is arranged substantially flush or behind an application end (15) of the device prior to actuation and after completion of injection.

Respectfully submitted

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